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91-300

No.

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

NATIONAL ASSOCIATION OF
PHARMACEUTICAL MANUFACTURERS,

Petitioner,

– against –

LOUIS W. SULLIVAN,
Secretary of Health and Human Services, et al.,

Respondents.

CROSS PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

CROSS PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The District of Columbia Court of Appeals declined to direct FDA to remedy continuing violations of a statutory 180-day time period for the taking of administrative action on Abbreviated New Drug Applications. The questions presented are:

1. May an agency be permitted to indefinitely avoid any judicial enforcement of a Congressionally mandated time period for the completion of administrative action on the ground that a court should not interfere with the agency's unilateral decision regarding the allocation of its resources?

2. Should the Supreme Court resolve the conflict between the circuits on the above issue as between the decision of the D.C. Circuit below and the decision of the Ninth Circuit in *Soler v. Scott et al.*, No. 89-16051 (9th Cir. August 1, 1991) (Appendix 10a-39a)?

PARTIES TO THE PROCEEDING

The petitioner herein, the NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS ("NAPM") is a trade association and was granted permission to intervene as a party below by the Court of Appeals. The other parties to the proceeding were the original petitioner, BARR LABORATORIES, INC., and the respondent administrative agencies DEPARTMENT OF HEALTH AND HUMAN SERVICES and the FOOD AND DRUG ADMINISTRATION,[1] together with their responsible officials, LOUIS W. SULLIVAN, Secretary of Health and Human Services, DAVID A. KESSLER, Commissioner, the Food and Drug Administration, CARL C. PECK, Director,

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[1] The Food and Drug Administration, referred to herein as FDA, is the division within the Department of Health and Human Services, which administers the responsibilities of that Agency under the Federal Food, Drug, & Cosmetic Act 21 U.S.C. §301 et seq.

FDA Center for Drug Evaluation and Research.

The parties before this Court are the same as those in the proceeding below, except that the petition for mandamus filed below originally named James S. Benson as a respondent because he was then the Acting Commissioner of the Food and Drug Administration. Thereafter, the present Commissioner was substituted as a party respondent.

CERTIFICATION UNDER RULE 29.1

The petitioner herein, the National Association of Pharmaceutical Manufacturers is a trade association. It has no parent companies, subsidiaries or affiliates.

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NATIONAL ASSOCIATION OF
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- against -

LOUIS W. SULLIVAN,
Secretary of Health and Human
Services, et al.

Respondents,

Cross Petition for Writ of Certiorari
to the United States Court of Appeals
for the District of Columbia Circuit

CROSS PETITION FOR WRIT OF CERTIORARI

The National Association of Pharmaceutical Manufacturers hereby prays that this Court grant the present Cross Petition for a Writ of Certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit together with the

Petition for Writ of Certiorari previously filed with this Court in *Barr Laboratories, Inc. v. Louis W. Sullivan et al.* (October Term 91-81).

OPINIONS BELOW

The opinion of the Court of Appeals is reported at In Re Barr Laboratories, 930 F.2d 72 (D.C. Cir., 1991) and is set forth in the Appendix hereto. Because this case involves a ruling on a petition for a Writ of Mandamus (first filed in the Court of Appeals), relating to a failure by FDA to act within 180 days as required by statute, there is no decision of the District Court or Agency administrative record to be reproduced.

JURISDICTION

The judgment of the Court of Appeals for the District of Columbia Circuit was entered April 16, 1991. This Cross

Petition is being filed pursuant to Supreme Court Rule 12.3. A petition for writ of certiorari by another party was filed by Barr Laboratories, Inc. (October Term 91-81) and was received by the instant cross petitioning party on July 17, 1991. Jurisdiction in the Court of Appeals was founded on the All Writs Act, 28 U.S.C. §1651, and 21 U.S.C. §355(h). The jurisdiction of this Court is invoked pursuant to 28 U.S.C. §1254(1).

STATUTES INVOLVED

5 U.S.C. §706

> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court

shall --

(1) compel agency action unlawfully withheld or unreasonably delayed . . . .

* * * *

21 U.S.C. §355(j)(4)(A)

Within one hundred and eighty days of the initial receipt of an [Abbreviated New Drug Application] or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

STATEMENT OF THE CASE

This proceeding presents for resolution vital issues relating to the implementation of statutory deadlines under the Federal Food, Drug and Cosmetic Act - and even more crucially, the entire relationship between the Courts and

administrative agencies in securing agency compliance with Congressional directives for timely and efficient agency action.

In a ruling fraught with ominous implications for an era of reduced budget appropriations, the Court of Appeals ruled that a Court should abstain from remedying across-the-board agency violations of an express statutory deadline, where the agency asserts that it alone should have the right to determine agency allocation of resources.

NAPM is a national trade association, which during the past 35 years has been the leading spokesman for the generic drug industry in the United States. NAPM members include manufacturers, distributors, wholesalers, and their affiliates, who supply the American public with generic multi-source drugs and related products.

NAPM has long played a key role in

representing industry viewpoints before the Courts, Congress, State Legislatures, and various administrative agencies, including FDA.[2] It is the principal commitment of NAPM to serve industry, consumers, and health care professionals by promoting and advancing their shared interest in the competitive marketplace availability of safe and effective drugs, at reasonable prices.

The case below arose from a petition originally filed by Barr Laboratories, Inc. ("Barr")[3] in the Court of Appeals, on July 31, 1990, seeking a writ of mandamus to compel FDA to act promptly upon its numerous pending applications for

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[2] *See e.g., National Association of Pharmaceutical Manufacturers v. Ayerst Laboratories*, 850 F.2d 904 (2d Cir. 1988); *National Association of Pharmaceutical Manufacturers v. Food and Drug Administration*, 637 F.2d 877 (2d Cir. 1981); *National Nutritional Foods Association and National Association of Pharmaceutical Manufacturers, et al. v. Kennedy, Commissioner of Food and Drugs*, 572 F.2d 377 (2d Cir. 1978).

[3] Barr is not a member of NAPM.

approval by the Agency for the marketing of generic prescription drug products by Barr. Barr alleged that the Court of Appeals had jurisdiction over the FDA's inaction pursuant to 21 U.S.C. §355(h), 5 U.S.C. §706, 28 U.S.C. §1331, and 28 U.S.C. §1651.[4]

Under a 1984 Amendment to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §355, Barr and other generic drug

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[4] The D.C. Circuit has held that the Court of Appeals has exclusive jurisdiction to entertain such a petition as regards a delay where a final order, when issued, would be appealable to a Court of Appeals. *See Telecommunications Research and Action Center v. Federal Communications Commission "TRAC"*, 750 F.2d 70, 77-78 (D.C. Cir. 1984). *But cf. Cutler v. Hayes*, 818 F.2d 879, 887 n.61 (D.C. Cir. 1987). New drug approvals are subject to such a provision. Although Court of Appeals jurisdiction under the All Writs Act is undoubtedly available here, an interesting collateral question for the Court's determination will be whether the Court of Appeals - rather than the District Court - truly is the exclusive and most suitable forum for resolution of these questions. The lower court's reluctance to grant any of the traditional forms of relief for delay of administrative action may in part stem from the unsuitability of the Court of Appeals as a forum for ongoing development of a factual record to decide such issues. So long as jurisdiction of the Court of Appeals is deemed "exclusive", however, litigants under the lower court's opinion are left with no alternative remedy.

manufacturers are entitled to file an "Abbreviated New Drug Application" (ANDA) which shows, *inter alia*, that their generic versions of a previously marketed product is "bioequivalent" to the previously approved pioneer drug and therefore suitable for safe marketing and distribution in the United States.[5] In response to earlier FDA delays in implementing the generic drug approval process,[6] Congress has specifically directed that "[w]ithin one hundred and

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[5] The background and purpose of this legislation were noted by this Court in *Eli Lilly & Co. v. Medtronic, Inc.*, __ U.S. __ , 110 S. Ct. 2683 (1990).

[6] FDA was previously required to act on new drug applications within 180-days of the "filing" of all new drug applications. For many years, FDA utilized a procedure of refusing to consider the application "filed" for months and even years after initial receipt. *See Durovic v. Richardson*, 479 F.2d 242, 245-46 (7th Cir.), *cert. denied*, 414 U.S. 944 (1973); *Newport Pharmaceuticals Int'l, Inc. v. Schweiker, [1981-82 Transfer Binder] Food Drug Cosmetic Law Reporter (CCH), ¶38,148 (D.D.C. December 2, 1981); IMS Ltd. v. Schweiker*, [1981 Transfer Binder] Food Drug Cosmetic Law Reporter (CCH), ¶38,104 (C.D.Ca. March 31, 1981). The 1984 Amendment ended this ploy for ANDAs by specifically requiring action within 180 days of <u>initial receipt</u>.

eighty days of the initial receipt of an [ANDA] . . . , the [FDA] shall approve or disapprove the application." 21 U.S.C. §355(j)(4)(A) (1988).

Barr's petition and supporting papers set forth in dramatic detail a course of administrative conduct which has rendered the Congressional 180 day deadline a total nullity. It was shown that the Agency had experienced a temporary personnel crisis in the summer of 1988, when a scandal had beset its generic drug division. (Appendix 3a). Delays in ANDA processing were thus at first understandable. The delays continued, however, and have now been perpetuated as FDA unilaterally implemented a permanent policy of treating the 180 day deadline as non-mandatory.[7] As a consequence, not only Barr's applications, but all ANDA applications,

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[7] This was done without engaging in any rulemaking proceedings under the APA.

including those of NAPM's members, were and are constantly being processed by FDA at a sluggish and unpredictable pace, in violation of the 180-day Congressional directive.[8]

As noted by the Court of Appeals:

> The FDA contests Barr's story only in the details. Whereas Barr calculates that the FDA took an average of 336 days to process past generic drug applications, Pet. Br. at 8, the FDA sets the figure at 262 days and estimates the response times for certain pending applications at between 389 and 669 days, Resp.Br. at 7. In other words, by the FDA's own account, its expected future delay will range from more than <u>double</u> the

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[8] NAPM does not suggest that FDA has not made any effort to improve the overall pace of its ANDA reviews. The grievance below and here is that FDA -- as a matter of policy -- continues to treat the 180-day time period as non-mandatory. For example, FDA officials have recently indicated that at some time in the future (but not for at least six months) the Agency may establish a "goal" for acting on about 20 ANDAs each month. Washington Drug Letter, August 5, 1991, at 1-2. NAPM applauds such action, which, if it is implemented would be a vast improvement. But this also represents nothing less than FDA's rewriting of the statute. The Act does not say that FDA should act on any given number of ANDAs per month, but rather that all ANDAs should be acted on within 180 days of initial receipt. Under FDA's present approach, it is apparent that absent a Court directive, the Agency will never come into compliance with the statute.

> allotted time to nearly quadruple. Even in the FDA's view, the delays are severe.

930 F.2d 74 (Appendix 3a) (emphasis in original).

Quite naturally, the relief sought by Barr below related only to securing action by FDA on its own pending ANDAs. When the filing of the petition for writ of mandamus became publicly known, NAPM sought and obtained leave to intervene as a party in the proceedings for the purpose of setting forth the position and views of the generic industry as a whole, from a public policy perspective.

NAPM therefore generally supported Barr's position, but argued below that giving only one company such as Barr relief under circumstances where the Agency was violating the deadline as to all ANDAs, was not the optimum resolution of this issue. NAPM requested the Court of Appeals to issue an Order directing the

Agency to comply generally with the 180-day statutory deadline, and if necessary, to retain jurisdiction for the purpose of supervising the FDA's progress in achieving compliance with the statutory directive.[9]

NAPM argued that the problem of FDA delay stemmed from the Agency's erroneous view that it had the right as a matter of discretion to disregard the 180 day statutory deadline as a matter of resource allocation policy. NAPM was and remains convinced that if a Court would find the deadline to be mandatory, and direct FDA upon a reasonable schedule to bring itself into compliance with the deadline, that the Agency undoubtedly could and would do so.

This was fully confirmed by FDA counsel at the oral argument before the

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[9] *See e.g. Cutler v. Hayes*, 818 F.2d 879, 899 n.169 (D.C. Cir. 1987).

Court of Appeals:

> Question: Suppose we issued an order, though, of some kind which, incidentally -- suppose we took the position of the intervenor, that we mandated the FDA to reach the 180-day deadline for everyone, not just Barr? Are you saying the FDA would refuse to comply with an order of this Court?
>
> Mr. Kell: I believe that the FDA would try its mightiest to comply with an order of this Court, and I believe it would do so out of its good-faith attempt to meet its statutory duties . . .[10]

The decision of the Court of Appeals below, however, failed to *require* FDA to take *any* remedial action. The Court correctly held (contrary to FDA's assertions) that the 180-day ANDA processing deadline is indeed mandatory. The Court further found that FDA had repeatedly and consistently violated that

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[10] *See* Transcript of Proceedings, *Barr Laboratories v. Sullivan*, No. 91-1402, United States Court of Appeals for the District of Columbia Circuit, February 19, 1991 at page 23. Copies of the transcript of oral argument have been lodged with the Clerk of the Court.

mandate and that the violations could be expected to continue.

Yet the Court held that it would not "assume command over an Agency's choice of priorities" (Appendix 4a, 7a-8a).[11] The Court found that "the impact of FDA's sluggish pace on the public health is effectively irrelevant" (Appendix 6a) because it had not been shown that Barr had been singled out for mistreatment, and because Agency scientists whose resources would have to be called upon to remedy the Agency's dereliction "presumably have not just been twiddling their thumbs." (Appendix 6a). The Court further held that because everyone's rights were being violated, no one -- including Barr -- was entitled to any relief. (Appendix 7a

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[11] As to possible questions of whether the Court of Appeals is a suitable forum for factually resolving these types of issues in the first instance, see note 4, *supra*.

-9a).[12]

Barr Laboratories has previously filed a petition for a writ of certiorari (October Term No. 91-81) and NAPM generally concurs therein, and respectfully urges the Court to grant such petition. NAPM has found it necessary, however, to file this cross petition because, once again, the issues as presented and relief requested by Barr are believed to be too narrow to fully address the major public interest and policy issues at stake.[13]

NAPM respectfully believes that the decision of the D.C. Court of Appeals has

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[12] Incongruously, the D.C. Circuit stated that it would have granted relief if Barr could have shown that only its applications were being delayed. (Appendix 6a-7a). Under this rationale, a relatively minor public injury -- limited to one company -- is appropriate for judicial relief, while a major violation affecting the entire industry and the consuming public is beyond the scope of judicial intervention.

[13] *See particularly* Supreme Court Rule 14.1(a) as to which issues will be considered by the Court upon a writ of certiorari.

sent FDA and all other administrative agencies the worst possible signal as to required Agency compliance with statutory deadlines and directives. FDA can hardly be expected to "try its mightiest" (or even at all)[14] to comply with the 180-day time period when the Court of Appeals has announced that so long as it fails to do so across the board for all ANDAs, no judicial relief will ever be available. The decision of the Court of Appeals represents a significant step backward in administrative jurisprudence; is in clear conflict with a recent decision of the United States Court of Appeals for the Ninth Circuit; and the critical public policy issues involved should be resolved

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[14] FDA has previously indicated to Congress that it believes that it should be allowed a period of at least one year to conduct ANDA reviews. H.R. Rep. No. 857, Pt. 1, 98th Cong., 2d Sess. 19 (1984). Congress rejected this and enacted the 180-day deadline. By its actions, FDA is thus overriding Congress' express determination on this issue.

promptly by this Court by grant of the petitions for writ of certiorari.

REASONS FOR GRANTING THE WRIT

I. THE D.C. COURT OF APPEALS' DECISION, IF NOT CORRECTED, WILL DEPRIVE AMERICAN CONSUMERS AND INDUSTRY OF THE CONGRESSIONALLY MANDATED BENEFITS OF TIMELY GENERIC DRUG APPROVALS AND ALSO WILL ENCOURAGE OTHER ADMINISTRATIVE AGENCIES TO DISREGARD CONGRESSIONALLY DIRECTED TIMETABLES.

For the first time, an Appellate Court has held that FDA may continuously and permanently violate an express statutory timetable without being subject to any judicial sanction.[15] This clearly raises an important question of Federal law, which should be decided by this Court. The public policy implications of

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[15] *Compare Cutler v. Hayes*, 818 F.2d 879 (D.C. Cir. 1987); *Public Citizen Health Research Group v. Commissioner, Food and Drug Administration*, 740 F.2d 21 (D.C. Cir. 1984); *American Public Health Association v. Veneman*, 349 F. Supp. 1311 (D.D.C. 1972).

the ruling by the D.C. Court of Appeals are immense.[16]

First, the integrity of the ANDA process is one which affects virtually every American household. FDA's present approach to approvals has made the planning and application process for ANDAs totally unpredictable. Generic drug companies need to be able to plan the timing of their introduction of generic drug products with some degree of certainty such that when the products are

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[16] The Court of Appeals suggests that petitioners take their grievance to Congress. (Appendix 6a). Congress, however, in the 1984 Amendment has already addressed the issue by setting its 180-day time limit. See note 19, *infra*. Moreover, the 1984 Amendment was a legislative compromise under which brand name companies were granted extensions of patent terms on pharmaceutical inventions in return for the enactment of the expedited post-patent ANDA generic drug approval system. *Eli Lilly & Co. v. Medtronic, supra*, 110 S.Ct. 2683; H.R. Rep. No. 857, Pt. 1, 98th Cong., 2d Sess. 19 (1984). As a result of FDA action and the lower court ruling, one-half of the legislative bargain has been effectively vitiated. It is the judicial function to remedy such violations and unfair and unreasonable to suggest that petitioners must or could again go to Congress. See also transcript of Oral Argument before Court of Appeals. lodged with the Clerk of the Court, n.10, *supra*, at pgs. 7, 10, 18, 33, and 34.

ultimately approved by FDA, they will be suitable for the needs of the consumer marketplace. The slow and unsteady pace of FDA actions and approvals will thus have an inevitable chilling effect on the entire process of generic drug introductions into the United States market.

The lower Court declined to grant relief even though it expressly recognized the above and other public policy concerns:

> Barr's interest, we may assume, is entirely commercial. But it makes money getting useful drugs into the hands of sick people. Of course, the "bioequivalents" of the drugs covered by these applications are, by definition, already available -- but at a higher price, which makes the stake appear pecuniary. But for poorer people -- the users for whom access to generic drugs is most important -- a pecuniary saving on drugs may have important health benefits. The difference between sinking, say 3% and 20% of one's income into pharmaceuticals spells a large difference in the range of economically accessible food and shelter.

> The prevalence of health insurance hardly disposes of these complications. Much of the American population is uncovered by medical insurance -- predominantly, in all likelihood, people for whom access to generic drugs is especially important. Moreover, for those who do buy private health insurance, unavailability of generic drugs spells higher premiums and again less income available for food, shelter, and every other item that may contribute to health and well-being. Similarly, given limits on congressional and taxpayer willingness to subsidize health care, the unavailability of cheap drugs means fewer resources for other aspects of health care.

930 F.2d at 75 (Appendix 5a-6a).

As further noted by the Court of Appeals,

> Congress sought to get generic drugs into the hands of patients at reasonable prices -- fast. The record before us reflects a defeat of those hopes.

930 F.2d at 76 (Appendix 8a).

> The issue before us, then, is not whether the FDA's sluggishness has violated a statutory mandate -- it has -- but whether we should exercise our equitable powers to enforce the deadline.

930 F.2d at 74 (Appendix 4a).

In light of the Court's own language,

it is hard to imagine a more compelling case for insisting on at least an eventual compliance for all with the statutory 180-day timetable.[17] Nonetheless, the lower Court believed that the issue was a "problem for the political branches to work out." *Id.* at 75 (Appendix 6a). In so doing, the Court completely abdicated its judicial responsibility under the Administrative Procedure Act, 5 U.S.C. §706(1), which mandates that the courts compel agency action unreasonably or

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[17] While it is true that relief for Barr alone would not by itself solve the overall problem raised here, we respectfully believe that the lower court made too much of this and overlooked the fact that granting relief at the very least to Barr would have forced FDA to begin moving in the right direction. Other companies could be expected to apply for similar relief and eventually FDA would surely come into compliance. NAPM continues to believe that such a piecemeal process is wasteful, time consuming and unfair. The correct approach is for the Court to direct overall FDA compliance with the statute on a reasonable timetable. Barr's remedy, to which it is surely entitled under the Administrative Procedure Act, would thus be secured in a fair and orderly manner as part of such overall Agency compliance.

unlawfully withheld.[18]

Moreover, in these times of lean budgets, Congress may have no more practical way to control agency priorities than by imposing specific time limits for the implementation of various administrative activities. Now, all such Congressional efforts may be thwarted for all time to come by any agency's expedient resort to the argument that it prefers to allocate its limited resources in another manner. While an agency has discretion in determining the allocation of its resources, that discretion must yield to the express will of Congress. Insofar as the FDA's priorities are concerned and

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[18] Interestingly, the argument in the Court below focused on the issue of whether the word "shall" in 21 U.S.C. §355(j)(4)(A) imposed a mandatory 180-day time period obligation on FDA. The D.C. Circuit answered that issue in the affirmative. The D.C. Circuit, however, ignored the word "shall" which appears in the APA, 5 U.S.C. §706(1), in determining whether that statute imposed a similar obligation upon a reviewing court to compel delayed agency action.

insofar as ANDA processing is concerned, Congress has unequivocally set forth what the FDA's priorities are by including the mandatory language within 21 U.S.C. §355(j)(4)(A).[19]

The approach of the D.C. Circuit in sanctioning an open-ended FDA policy of violating the statute is so seriously at odds with traditional notions of administrative agency accountability as to warrant prompt and immediate review by this Court.[20]

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[19] As stated in H.R. REP. No. 857, 98th Cong., *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2660 (Legislative History of the Drug Price Competition and Patent Term Restoration Act), "Paragraph (4)(A) ***requires*** *FDA to approve or disapprove an ANDA within 180 days of initial receipt of the application. The Committee recognizes that extensions may be necessary so the bill permits extensions of this period for so long as the applicant and the FDA may agree upon.* (Emphasis added).

[20] *See generally General Motors Corp. v. United States*, __ U.S. __, 110 S. Ct. 2528, 2533 (1990); *Brock v. Pierce County*, 476 U.S. 253, 260 n.7 (1986); *Costle v. Pacific Legal Foundation*, 445 U.S. 198, 220, n.14 (1980); *Smith v. Illinois Bell Tel Co.*, 270 U.S. 587, 591 (1926); *Interstate Commerce Commission v. United States ex. rel. Humboldt S.S. Co.*, 224 U.S. 474 (1912). *See also Cutler, supra*, 818 F.2d 879.

II. THIS COURT SHOULD RESOLVE THE CONFLICT AMONG THE CIRCUITS AS REGARDS THE PROPER ROLE OF THE COURTS IN COMPELLING AGENCY ACTION IN THE FACE OF AN AGENCY ASSERTION OF DISCRETION BASED ON ALLEGED RESOURCE CONSTRAINTS.

The hands-off approach of the D.C. Circuit in dealing with FDA's failure to comply with the statutory mandate is in stark contrast to, and conflict with a recent decision of the United States Court of Appeals for the Ninth Circuit in *Soler v. Scott, et al.* No. 89-16051 (9th Cir. August 1, 1991), 1991 U.S. App. LEXIS 17423.[21]

Soler involved the application of Section 701 of the Immigration Reform and Control Act of 1986, 8 U.S.C. §1252(i). Congress enacted this statute to accomplish a single objective: to require the Immigration and Naturalization Service

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[21] This opinion, which is not yet officially reported, is set forth in the Appendix hereto at 10a-39a.

to abandon its long standing practice of postponing alien prisoner deportation hearings until after the expiration of a prisoner's sentence.

The INS policy was, and apparently still is, to wait until an alien prisoner completed his or her sentence before even scheduling a hearing on the issue of whether the prisoner should be deported. As a consequence, aliens were not deported promptly and remained in prison and in the United States for a long time after the expiration of their sentences. Congress' primary concern was that this imposed an economic burden on Federal and particularly State prison resources. (Appendix 11a-12a).

The 1986 Statute sought to end this practice by directing the INS to commence deportation hearings as expeditiously as possible after the date of conviction. Unwilling to mend its ways, INS

nevertheless continued its old practice of waiting until long after the date of conviction, thereby totally frustrating the Congressional intent.

The Ninth Circuit held, as did the D.C. Circuit here, that the words of the applicable statute are mandatory and that the INS' continuation of the old policy was clearly violative of the text and purpose of the new statute:

> If Soler's allegations are true, the INS has decided not to consider the date of conviction at all in scheduling prisoner deportation hearings, but instead to be guided by a date of its own choosing, a date much later than the one chosen by Congress.

(Appendix 17a).

In a context which is very similar to the one raised in this petition, the Ninth Circuit, however, went on to reject the INS' arguments of administrative discretion as to resource allocation and affirmed that a cause of action existed

both under the Administrative Procedure Act 5 U.S.C. §706(1) and Mandamus and Venue Act of 1962, 28 U.S.C. §1361 (1988):

> The INS' only argument in support of its alleged policy of delay is that Section 701 imposes upon it too great a fiscal burden. Congress, however, has concluded the INS is more capable of handling the burden of the deportable alien prisoners than the Federal and State prison systems and the burden falls more appropriately on the Federal government.

(Appendix 18a at footnote 1). The Court thus held that "mandamus is an appropriate remedy to compel compliance with Congress' unequivocal mandate." (Appendix 25a).

The conflict between the decisions of the D.C. Circuit and the Ninth Circuit as to the policy of judicial enforcement in the face of an agency's "limited resources" claim is thus apparent. If anything, the public policy factors relating to compelling agency action to ensure the most expeditious availability

of generic drugs would seem to be of an even higher order than compelling the most economical procedure for completion of deportation hearings for convicted aliens. Moreover, Section 701 at issue before the Ninth Circuit required only that the hearings be conducted "as expeditiously as possible" while the Food, Drug and Cosmetic Act sets a specific and unambiguous 180-day timetable for FDA actions on ANDAs.

The decision of the Ninth Circuit is clearly more in accord with traditional notions of administrative accountability and judicial redress for plainly demonstrated administrative violations of law. Given the significance of this issue and its potential applicability to virtually every administrative agency, it is important that the correct judicial approach towards this problem not be left in doubt. Certiorari should therefore be

granted to resolve this conflict among the circuits.

CONCLUSION

For the reasons set forth herein, NAPM respectfully concludes that the public interest fully warrants prompt review by this Court of the important public policy issues raised by the D.C. Circuit decision. The cross petition for writ of certiorari is intended to present the full scope of this issue to the Court so that the legitimacy of FDA's across the board failure to follow the 180-day timetable for ANDA approvals can be decided.

It is therefore respectfully requested that NAPM's cross petition for writ of certiorari along with the petition for writ of certiorari previously filed by Barr should be granted and that the writs should issue to review the judgment of the

Court of Appeals for the District of Columbia Circuit.

Respectfully submitted,

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APPENDIX

APPENDIX

UNITED STATES COURT OF APPEALS
DISTRICT OF COLUMBIA CIRCUIT

No. 90-1402

IN RE BARR LABORATORIES, INC.,
Petitioner.

On Petition for Writ of Mandamus

Argued Feb. 19, 1991

Decided April 16, 1991

As Amended April 23, 1991

Eric L. Hirschhorn, with whom Bruce L. Downey, Washington, D.C., was on the brief for petitioners.

Jacob Laufer of the bar of the Supreme Court of the State of New York, pro hac vice, by special leave of the Court, with whom John M. Desiderio, James S. Rubin and Steven Shapiro, New York City, were on the brief, for intervenor.

Gerald C. Kell, Atty., Dept. of Justice with whom Stuart M. Gerson, Asst. Atty. Gen. and John R. Fleder, Washington, D.C., Director, Office of Consumer Litigation Dept. of Justice and Eric M. Blumberg, Rockville, Md., Associate Chief Counsel for Enforcement, Food and Drug Admin. were on the brief, for respondent.

Before SILBERMAN, WILLIAMS and RANDOLPH, Circuit Judges.

Opinion for the Court filed by Circuit Judge STEPHEN F. WILLIAMS.

STEPHEN F. WILLIAMS, Circuit Judge:

Barr Laboratories has filed a petition in this court, see *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70, 74-79 (D.C. Cir. 1984) ("TRAC"), seeking a writ of mandamus to compel the Food and Drug Administration to act promptly in either approving or disapproving 23 of Barr's abbreviated new drug applications and abbreviated antibiotic applications (collectively, "generic drug applications"). Though we agree with Barr that FDA's sluggish pace violates a statutory deadline, we conclude that this is not an appropriate case for equitable relief. While judicial intervention could assist Barr, it would likely impose offsetting burdens on equally worthy generic drug producers, equally wronged by the agency's delay. Moreover, while prompt disposition of Barr's applications would benefit users of generic drugs, so would the disposition of other companies' applications, which relief for Barr would further delay.

* * * *

Under a 1984 amendment to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (1988), a producer of generic drugs may file applications that rely heavily on approved applications for "listed" (generally name-brand) drugs. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. This expedited process permits generic drug applications to piggy-back on clinical findings that FDA has already embraced. Accordingly, the application must demonstrate, among other things, that the generic drug is the "bioequivalent" of the listed drug and that it is properly manufactured and labeled. See 21 U.S.C. § 355(j)(2)(A).

Congress specified that "[w]ithin one hundred and eighty days of the initial receipt of [a generic drug]

application . . . or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application." 21 U.S.C. § 355(j)(4)(A). Under regulations not challenged here, an applicant that files a "major" amendment to its application, either at the agency's behest or on its own initiative, is deemed to have consented to a new review period that may last up to an additional 180 days. See 21 C.F.R. §§ 314.60, 314.100(c) (1990).

Barr claims that the FDA has repeatedly violated the 180-day deadline in processing its generic drug applications. According to Barr, the agency has (in some cases) ignored the deadline altogether and (in others) improperly skirted it by waiting until the end of the 180-day period before provisionally "denying" the applications on the basis of spurious technicalities.

The FDA contests Barr's story only in the details. Whereas Barr calculates that the FDA took an average of 336 days to process past generic drug applications, Pet.Br. at 8, the FDA sets the figure at 262 days and estimates the response times for certain pending applications at between 389 and 669 days, Resp.Br. at 7. In other words, by the FDA's own account, its expected future delay will range from more than *double* the allotted time to nearly *quadruple*. Even in the FDA's view, the delays are severe. It explains the lag as the product of a personnel crisis that began in the summer of 1988, when scandal beset its generic drug division, forcing out some employees and diverting others from their usual work. See Burlington Declaration, Exhibit B, at 9-15.

Effectively conceding that it has violated the 180-day provision, the government answers that the deadline is only "directory". It reasons that because Congress did not specify a "consequence" for noncompliance, the provision—though seemingly mandatory—is only a kind of policy recommendation. The cases the government cites for this idea, e.g., *Brock v. Pierce County*, 476 U.S.

253, 259, 106 S.Ct. 1834, 1838, 90 L.Ed.2d 248 (1986); *Ralpho v. Bell*, 569 F.2d 607, 626-28 (D.C. Cir. 1977); *Fort Worth Nat'l Corp. v. FSLIC*, 469 F.2d 47, 58 (5th Cir. 1972); *Maryland Casualty Co. v. Cardillo*, 99 F.2d 432, 434 (D.C. Cir. 1938), are inapposite. All of them considered the separate problem of whether, as a consequence of missing a relevant statutory deadline, an agency loses jurisdiction over a case or issue; all (unsurprisingly) rejected that view. None of the cases considered the problem at issue here: whether an agency acts lawfully in ignoring a facially mandatory statutory deadline. In fact, the court in *Fort Worth* suggested that, in general, the "proper remedy" of a party seeking to enforce a statutory deadline is not to challenge the legitimacy of post-deadline agency actions, but "to apply for a court order compelling the [agency] to act." 469 F.2d at 58. That, of course, is just what Barr is doing.

The issue before us, then, is not whether the FDA's sluggishness has violated a statutory mandate—it has—but whether we should exercise our equitable powers to enforce the deadline. Equitable relief, particularly mandamus, does not necessarily follow a finding of a violation: respect for the autonomy and comparative institutional advantage of the executive branch has traditionally made courts slow to assume command over an agency's choice of priorities. See, e.g., *In re Monroe Communications Corp.*, 840 F.2d 942, 946 (D.C. Cir. 1988).

Our leading case in this area, *TRAC*, identified six principles that have helped courts determine when mandamus is an appropriate remedy for agency delay:

> (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of eco-

> nomic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.' "

750 F.2d at 80 (citations and internal quotes omitted). Here we may assume that Congress's 180-day deadline indeed supplies content for item one's "rule of reason", but a finding that delay is unreasonable does not, alone, justify judicial intervention. E.g., *In re Center for Auto Safety*, 793 F.2d 1346, 1354 (D.C. Cir. 1986).

TRAC's third factor (which overlaps with the fifth, at least in this context) asks whether the case is primarily about "human health and welfare" or "economic regulation". Here, at least, categorization of the values at stake is elusive. It is also largely irrelevant in light of *TRAC's* fourth consideration—the effect of relief on competing agency activities.

Barr's interest, we may assume, is entirely commercial. But it makes money getting useful drugs into the hands of sick people. Of course the "bioequivalents" of the drugs covered by these applications are, by definition, already available—but at a higher price, which makes the stake appear pecuniary. But for poorer people—the users for whom access to generic drugs is most important—a pecuniary saving on drugs may have important health benefits. The difference between sinking, say, 3% and 20% of one's income into pharmaceuticals spells a large difference in the range of economically accessible food and shelter.

The prevalence of health insurance hardly disposes of these complications. Much of the American population is

uncovered by medical insurance—predominantly, in all likelihood, people for whom access to generic drugs is especially important. Moreover, for those who do buy private health insurance, unavailability of generic drugs spells higher premiums and again less income available for food, shelter, and every other item that may contribute to health and well-being. Similarly, given limits on congressional and taxpayer willingness to subsidize health care, the unavailability of cheap drugs means fewer resources for other aspects of health care.

But the impact of the FDA's sluggish pace on the public health is effectively irrelevant in light of our analysis of *TRAC's* fourth factor, the effect of relief on competing agency priorities. Assuming constant resources for the generic drug program, a judicial order putting Barr at the head of the queue simply moves all others back one space and produces no net gain. Agency officials not working on Barr's matters presumably have not just been "twiddl[ing] their thumbs". See *Board of Trade v. SEC*, 883 F.2d 525, 531 (7th Cir. 1989). Perhaps Congress should earmark more funds specifically to the generic drug program, cf. Intervenor's Br. at 9, but that is a problem for the political branches to work out.

If Barr had shown that the FDA had singled it out for mistreatment, judicial relief would then advance the cause of equal treatment and, despite the lack of any immediate net advancement of Congress's policy objectives, could make sense. Our cases considering agency delay have often asked whether it was "egregious", see *In re Monroe Communications Corp.*, 840 F.2d 942, 946 (D.C. Cir. 1988); *TRAC*, 750 F.2d at 80; *Public Citizen Health Research Group v. FDA*, 740 F.2d 21, 34 (D.C. Cir. 1984), and especially shabby treatment of one applicant would seem exactly that.

In fact, Barr's reply brief alleges that the FDA *has* vindictively singled it out for especially bad treatment. Reply Br. at 9-10. If Barr had asserted this claim

initially, we would be able to assess whether it was worth a special factual inquiry. See *TRAC*, 750 F.2d at 78. Given the vague and secondhand character of Barr's claim (Barr emphasizes a lone congressman's suspicions), that seems improbable, but as Barr raised the issue only in its reply, respect for the adversary process makes it inappropriate to address the claim at all. See *Golden Pacific Bancorp. v. Clarke*, 837 F.2d 509, 513 (D.C. Cir. 1988); *Carducci v. Regan*, 714 F.2d 171, 177 (D.C. Cir. 1983). And absent this claim, we have no reason to think that judicial intervention would advance either fairness or Congress's policy objectives.

In short, we have no basis for reordering agency priorities. The agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way. Such budget flexibility as Congress has allowed the agency is not for us to hijack. In one of the exceptionally rare cases where this court has actually issued an order compelling an agency to press forward with a specific project, *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983), we were persuaded, largely by agency concessions, that the project backed by plaintiff was plainly more "urgent" than any that the project's acceleration might retard. See *id.* at 1158. Nothing of the sort exists here. While Congress clearly intended a faster track for generic drug applications in general, it did not choose a super-priority for Barr, and it did not address the trade-off between strict compliance with the 180-day deadline and the FDA's disposition of its other projects with enough clarity to guide judicial intervention.

Barr tries to sidestep the resource-allocation issue by noting that the FDA itself has recently requested budget cuts from Congress. That request, filtered through the Office of Management and Budget, is the product of a complex set of policy tradeoffs; its size does not contradict

the FDA's claim that its resources are inadequate to satisfy an independently set timetable. In any event, even if the request reflected unsound judgment—a matter on which courts are completely unqualified to pass—the problems that flow from it are not ones that we can fix by reshuffling the agency's files.

The result would not change even if Barr could back up its insinuation that the FDA could act more efficiently if it tried. Reply Br. at 3, 7-8. We have no reason to think that a judicial decree advancing one applicant would cure FDA's incompetence, if it exists and even if it is severe. A court order could shift, but not lift, the burden that inefficiency inflicts on pharmaceutical suppliers and users. The agency could alleviate its own inefficiencies, perhaps through generic rulemaking, cf. *Heckler v. Campbell*, 461 U.S. 458, 103 S.Ct. 1952, 76 L.Ed.2d 66 (1983), or other simplifications of the review process—but judges have neither the capacity nor the authority to require such measures.

For its sixth item *TRAC* notes that "the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed." 750 F.2d at 80 (internal quotes omitted). But the issue of impropriety intersects with item four's sensitivity to the agency's legitimate priorities. Where the agency has manifested bad faith, as by singling someone out for bad treatment or asserting utter indifference to a congressional deadline, the agency will have a hard time claiming legitimacy for its priorities. Accordingly, the absence of bad faith, as here, is relevant to the appropriateness of mandamus. See *In re Monroe Communications Corp.*, 840 F.2d at 946-47.

* * * *

Congress sought to get generic drugs into the hands of patients at reasonable prices—fast. The record before us reflects a defeat of those hopes. There are probably remedies: more resources, more efficient use of those now

committed, elimination of the residual effects of the recently publicized scandals. For the reasons discussed, none is within our power, and a grant of Barr's petition is no remedy at all. For similar reasons, we see no point in maintaining constant supervision over the FDA's progress. We thus dismiss the suit, but invite Barr to refile should circumstances arise that would change the outcome of our analysis.

So ordered.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 89-16051

CARLOS SOLER,

Plaintiff-Appellant,

v.

ROGER F. SCOTT, Warden, FCI-Safford, AZ; UNITED STATES BUREAU OF PRISONS; U.S. IMMIGRATION AND NATURALIZATION SERVICE,

Defendants-Appellees.

Submitted Oct. 5, 1990.*

Decided Aug. 1, 1991.

Before BROWNING, GOODWIN AND RYMER, Circuit Judges.

BROWNING, J.

Section 701 of the Immigration Reform and Control Act of 1986 provides:

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* The panel unanimously finds this case appropriate for submission without oral argument pursuant to 9th Cir. R. 34-4 and Fed. R. App. P. 34(a).

> In the case of an alien who is convicted of an offense which makes the alien subject to deportation, the Attorney General [through the Immigration and Naturalization Service] shall begin any deportation proceeding as expeditiously as possible after the date of the conviction.

8 U.S.C. §1252(i) (1988).

Congress enacted Section 701 to accomplish a single objective: to require the INS to abandon its practice of postponing prisoner deportation hearings until after the expiration of a prisoner's sentence. Rather than deporting aliens promptly upon the expiration of their prison sentence, the INS waited until a prisoner completed his or her sentence before even scheduling a hearing to determine whether the prisoner would be deported. These aliens remained in prison while awaiting their deportation hearing. Congress concluded this practice of keeping aliens in prison after they had completed their sentence contributed to

prison overcrowding and imposed an unfair, unnecessary and expensive burden on limited federal and state resources. Congress enacted Section 701 to require the INS to begin deportation hearings as soon as possible after conviction so the question of deportation could be resolved before the prisoner's term expired, and if the prisoner was found deportable, deportation could be accomplished promptly. As Representative MacKay, who introduced Section 701 as a floor amendment to the Immigration Reform and Control Act, explained:

> [Section 701] addresses a narrow but a very important issue. It has to do with illegal aliens who are convicted of drug-related crimes, who under Federal law should be deported and who, under the policies of the Immigration and Naturalization Service, should be deported on an expedited basis.
>
> The policies require that deportation proceedings begin when a conviction takes place, the idea being that when the sentence is over, the person would be deported.

> Now, unfortunately, the very opposite is happening. These people are not being deported; the expedited procedure is not working; the local and State jails are jammed up[;] the Immigration and Naturalization Service has no incentive to give priority to these because the burden of inaction falls on State and local governments and not on the Federal system.
>
> This amendment provides . . . that deportation proceedings will begin when there is a conviction.

132 *Cong. Rec.* H9794 (October 9, 1986). Representative MacKay proved himself a poor prophet when he added: "I believe this amendment would lead very quickly to a changing of priorities in INS." *Id.*

In the Senate, then-Majority Leader Dole expressed concerns similar to those of Congressman MacKay, noting that the amendment would provide:

> authority for expeditious deportation of convicted felons. This is a particular concern of mine, since there are about 6,000 aliens currently in Federal prisons and many more in the State and local systems.

132 *Cong.Rec.* §16908 (October 17, 1986).

Senator Dole added:

> They are occupying space that is desperately needed. They are costing the taxpayers millions for their board and keep.

Id. at §16909.

Appellant Carlos Soler, a native of Cuba, entered the United States legally in 1970, and is currently in federal prison for a crime that may subject him to deportation. The INS filed a "Detainer," informing prison authorities that Soler might be deportable, but took no further action. A year after his conviction, Soler filed a *pro se* petition seeking an order to compel the INS to schedule and hold a prompt deportation hearing. Soler alleged "the INS has a long-standing policy of refusing to begin any deportation proceedings until after release from [Bureau of Prisons custody," and "has no intention" of holding his

hearing before that time "unless compelled to[ ] by this Court."

Soler further alleged that due to the INS policy, he will be forced to remain in prison beyond the expiration of his term while waiting for the INS to decide whether he should be deported: "By delaying actual [deportation] proceedings until after the incarceration for Petitioner's criminal conviction," Soler alleges, "existing government policy guarantees additional costs of incarceration during the post-incarceration proceedings; and this is precisely what Congress sought to avoid in enacting Title 8 U.S.C. §1252(i)."

The INS does not deny the existence of the policy Soler alleges, nor its consequences. Instead, the INS argues it is "under no duty enforceable by petitioner to accord him a deportation hearing before he completes his criminal

sentence. Moreover, any duty which may exist is discretionary, not ministerial in nature." We disagree.

I.

As Soler asserts, the INS' alleged policy is flatly inconsistent with the text and purpose of Section 701.

The words of the statute are mandatory: the "Attorney General [through the INS] shall begin any deportation proceeding as expeditiously as possible after the date of the conviction." 8 U.S.C. §1252(i) (emphasis added). The use of mandatory language strongly indicates Congress intended to limit INS discretion. See *United States v. Chavez*, 627 F.2d 953, 954-55 (9th Cir. 1980). Moreover, by specifically referring to "the date of the conviction," Congress plainly intended this date, not the prisoner's scheduled date for release, to be the benchmark for

scheduling deportation hearings. If Soler's allegations are true, the INS has decided not to consider the date of conviction at all in scheduling prisoner deportation hearings but instead to be guided by a date of its own choosing, a date much later than the one chosen by Congress.

By use of the phrase "as soon as possible" Congress gave the INS significant discretion in scheduling deportation hearings. It is clear from legislative history, however, that Congress left the INS no discretion to adopt a policy that fixes a departure point for the exercise of the scheduling discretion significantly later than the date Congress mandated, and necessarily postpones every deportation hearing beyond expiration of each individual alien's prison term.

Representative MacKay emphasized that

the singular purpose of Section 701 was to end the very practice Soler alleges persists. 132 *Cong. Rec.* H9794 (October 9, 1986). Congress' stated intent was to ease the chronic problem of prison overcrowding by "provid[ing] ... that deportation proceedings will begin when there is a conviction." *Id.* (emphasis added). Congress plainly did not intend to leave the INS discretion to adopt the very policy it was forbidding.[1]

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[1] For this reason, the INS' apparent interpretation of Section 701 is entitled to no deference. Courts "must reject administrative constructions which are contrary to clear congressional intent." *Chevron U.S.A., Inc. v. National Resources Defense Council*, 467 U.S. 837, 843 n.9 (1984). The INS' only argument in support of its alleged policy of delay is that Section 701 imposes upon it too great a fiscal burden. Congress, however, has concluded that the INS is more capable of handling the burden of deportable alien prisoners than the federal and state prison systems, and that the burden more appropriately falls exclusively upon the federal government. As Representative MacKay stated:

> I do not believe [Section 701] would be unduly disruptive on the Federal

II.

We conclude Soler's allegations state a cause of action under the Mandamus and Venue Act of 1962, 28 U.S.C. §1361 (1988), and the Administrative Procedure Act, 5 U.S.C. §§701-706 (1988).

A.

Assuming the facts to be as alleged, mandamus is an appropriate means of compelling the INS to schedule Soler's deportation hearing in a manner consistent with Section 701.

Mandamus may not be used to instruct an official how to exercise discretion. *See e.g., Marbury v. Madison* 5 U.S. (1 Cranch) 137, 170-71 (1803); *Wilmot v. Doyle*, 403 F.2d 811, 816 (9th Cir. 1969). Mandamus is appropriate when an official's

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> system. If it is disruptive on the Federal system, that is where the disruption should be instead of where it is now, which is in the State systems.

132 *Cong. Rec.* H9794 (October 9, 1986).

duty to act is ministerial in nature and so plain as to be free from doubt. *Moose v. United States*, 674 F.2d 1277, 1284 (9th Cir. 1982); *Elliot v. Weinberger*, 564 F.2d 1219, 1226 (9th Cir. 1977).[2] This does not mean an official's conduct is unreviewable because the official's responsibilities are in some respects discretionary. As the Supreme Court has long recognized, a "duty may be discretionary within limits. [The official] can not transgress those limits,

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[2] A duty may be plain even if the statute is ambiguous and "requires construction to determine the duties it creates. If the ... duty is clear after the court interprets the statute, the court has jurisdiction [under the Mandamus Act]." *Piledrivers' Local Union No. 2375 v. Smith*, 695 F.2d 390. 392 (9th Cir. 1982) (citations omitted). See also *Knuckles v. Weinberger*, 511 F.2d 1221, 1222 (9th Cir. 1975) ("once the court interprets the law, the defendant's duty will be clear"); *Roberts v. United States*, 176 U.S. 221, 231 (1900). Thus, the fact that legislative history is consulted in construing Section 701 does not preclude mandamus.

and if he does so, he may be controlled by injunction or mandamus to keep within them." *Work v. Rives*, 267 U.S. 175, 177 (1925) (Taft, C.J.). Thus, the "extent [of the officer's discretion] and the scope of judicial action in limiting it depend upon a proper interpretation of the particular statute and the congressional purpose." *Id* at 178. "In other words, even in an area generally left to agency discretion, there may well exist statutory or regulatory standards delimiting the scope or manner in which such discretion can be exercised. In these situations, mandamus will lie when the standards have been ignored or violated," *Carpet, Linoleum and Resilient Tile Layers, Local Union No. 419 v. Brown*, 656 F.2d 564, 566 (10th Cir. 1981) (quoting *Davis Associates, Inc. v. Secretary, Dep't of Hous. and Urban Dev.*, 498 F.2d 385, 389 n.5 (1st Cir. 1974)).

The cases of *Ganem v. Heckler*, 746 F.2d 844 (D.C. Cir. 1984), and *Commonwealth of Pennsylvania v. National Ass'n of Flood Insurers*, 520 F.2d 11 (3d Cir. 1975), are illustrative.

In *Ganem*, the petitioner sought mandamus to compel the Secretary of Health and Human Services to determine whether the nation of Iran discriminated against Americans in its social service programs. The Secretary was required by law to determine whether such discrimination existed, and, if it did not, to award benefits to eligible Iranians. *Ganem*, 746 F.2d at 846. The Secretary chose to determine the content of Iranian law only by direct contact with Iranian officials, a practical impossibility because of the interruption of diplomatic relations between the two nations. *Id.* at 847, 853. The court concluded the Secretary could be compelled by mandamus to adopt realistic

means for determining Iranian law and her failure to do so "completely contravened the purpose of the Act to make Social Security Benefits available to eligible Iranians. *Id.* at 853-54. The court recognized the Secretary retained "discretion in the method by which she chooses to determine foreign law, but that discretion must be exercised ... consistent with the statutory purposes." *Id.* at 854. "It is simply not within the Secretary's discretion," the court held, "to deprive entitled beneficiaries of their earned rights by virtue of a policy position that virtually assures the Secretary's inability to make a determination which the statute obligates her to make." *Id.* The Secretary's refusal to determine Iranian law by realistic means was "a clear abnegation of [her] statutory responsibilities," *Id.* at 848, and could be corrected by mandamus.

The statute involved in *Commonwealth of Pennsylvania* provided the Secretary of Housing and Urban Development "shall from time to time take such action as may be necessary in order to make information and data [relating to flood insurance] available to the public...." *Commonwealth of Pennsylvania*, 520 F.2d at 26 (quoting 42 U.S.C. §4020 (1988)). The court recognized that the phrase "as may be necessary" vested significant discretion in the Secretary to decide if and when information should be disseminated. *Id.* However, this discretion pertained only to when and how the Secretary acted, and did not "permit disobedience to the initial directive, implicit in the statutory framework." *Id.* (citing *Work*, 267 U.S. 175). Refusal to take this initial action would be a "total failure of the Secretary to perform [his] duties ..." *Id.* (emphasis in original), and warranted

mandamus relief.

In this case, Congress intended that "deportation proceedings begin which a conviction takes place, the idea being that when the sentence is over, the person would be deported." 132 *Cong. Rec.* H9794 (October 9, 1986) (remarks of Representative MacKay). A policy of delaying prisoner deportation hearings until the expiration of a prisoner's term "transgress[es] th[e] limits," *Work* 267 U.S. at 177, of any discretion delegated to the INS by Congress. Such a policy insures, by definition, that Congress' purpose will not be carried out. It is "a clear abnegation of [the INS] statutory responsibilit[y]," *Ganem*, 746 F.2d at 848, a "total failure of the [INS] to perform [its] duties." *Commonwealth of Pennsylvania*, 520 F.2d at 26. Mandamus is an appropriate remedy to compel compliance with Congress' unequivocal mandate.

B.

Soler has also stated a claim for relief under the Administrative Procedure Act.[3]

The APA provides, "The reviewing court shall -- (1) compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. §706; and [a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. §702. "These

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[3] Soler's petition does not rely upon the APA explicitly, but we are to construe his *pro se* pleadings liberally. See *Hughes v. Rowe*, 449 U.S. 5, 9 (1980); *United States v. Eatinger*, 902 F. 2d 1383, 1385 (9th Cir. 1990). Moreover, in *Japan Whaling Ass'n v. American Cetacean Soc.*, 478 U.S. 221, 228 & 231 n.4 (1986), a case involving no pro se parties, the Supreme Court treated a petition filed under the Mandamus Act to compel agency action as a claim for relief under the APA, reasoning that on the facts of the case the two forms of relief were "in essence" the same. We adopt the same approach.

sections of the APA create a right of judicial review of agency action unlawfully withheld." *Rank v. Nimmo*, 677 F.2d 692, 698 (9th Cir. 1982). See also *Carpet, Linoleum*, 656 F.2d at 566-67. Soler's complaint plainly states a claim under these provisions. The INS' refusal to comply with the clear congressional command to initiate deportation proceedings as soon as practicable after conviction is necessarily "agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. §706.

Judicial intervention at this stage is not premature. Though judicial review is limited to "final agency action," 5 U.S.C. §704, application by the INS of a policy of delaying deportation hearings for incarcerated aliens until the expiration of the alien's prison term, is a final agency decision not to follow the statutory mandate in that case. Where an

administrative decision "represent[s] agency recalcitrance ... in the face of a clear statutory duty ... of such magnitude that it amounts to an abdication of statutory responsibility ... the court has the power to order the agency to act to carry out its substantive statutory mandates." *Sierra Club v. Thomas*, 828 F.2d 783, 793 (D.C. Cir, 1987) (quoting *Public Citizen Health Research Group v. Commissioner, Food & Drug Admin.* 740 F.2d 21, 32 (D.C. Cir. 1984)). "[T]he agency might forever evade our review and thus escape its duties if we awaited final agency action before reviewing the[e] claim." *Id.* See also Public Citizen v. Bowen, 833 F.2d 364, 367 (D.C. Cir. 1987) ("In the nature of things, obviously, want of finality in the conventional sense cannot be a bar" to a claim that agency action was unlawfully withheld or unreasonably delayed within the meaning of

5 U.S.C. 706(1)).

Soler cannot be faulted for failing to exhaust administrative remedies: the INS concedes no administrative remedies are available to him under the circumstances of this case.

III.

The district court nevertheless dismissed Soler's complaint on the ground that Section 701 created no implied private right of action, citing *Gonzales v. INS*, 867 F.2d 1108 (8th Cir. 1989). The district court's conclusion that Soler's claim depends upon the existence of an implied private right of action under Section 701 was mistaken.

When a petitioner seeks to "compel agency action unlawfully withheld or unreasonably delayed," 5 U.S.C. §706(1), it is not necessary to determine whether the underlying statute creates a private

right of action. "The 'right of action' in such cases is expressly created by the Administrative Procedure Act .... A separate indication of congressional intent to make agency action reviewable under the APA is not necessary; instead, the rule is that the cause of action for review of such action is available absent some clear and convincing evidence of legislative intention to preclude review."[4] *Japan Whaling*, 478 U.S. at 231 n.4. See also *Sierra Club v. Peterson*, 705 F.2d 1475, 1478-79 (9th Cir. 1983).

The same is true of a claim under the Mandamus Act to "compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. §1361. In *Legal Aid Society of Alamedia County v.*

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[4] There is no indication in either the text or legislative history of Section 701 that Congress intended to preclude judicial review.

Brennan, 608 P.2d 1319 (9th Cir. 1979), we rejected the argument that a petitioner can proceed under the Mandamus Act only if the statute or regulation allegedly violated by the United States creates an implied private right of action. As we said in *Legal Aid Society*:

> Appellees do not seek recognition of a supplemental private enforcement mechanism. They do not seek damages for specific acts of discrimination against themselves. They ask only that the court review the government's own enforcement effort against the standards established by the Executive Order and regulations. Review of this sort is an ordinary element of administrative enforcement schemes, absent clear indication to the contrary. Since the only relief sought in such a suit is that government officials be required to perform the non-discretionary duties imposed upon them by the Executive Order and regulations, the action is by definition compatible with the scheme established by the order and regulations. The reluctance of courts to imply separate private enforcement rights from statutes or regulations which provide explicitly only for government enforcement procedures and penalties, see e.g., *Cort v. Ash*, 422 U.S. 66, 78-80 ... is not applicable ...

Id. at 1332. Similarly, Soler "do[es] not seek recognition of a supplemental private enforcement mechanism: but review by mandamus, "an ordinary element of administrative enforcement schemes." *Id.* Thus, "[t]he reluctance of courts to imply private enforcement rights... is not applicable." *Id.* In sum, a petitioner who has alleged a cause of action under the APA or the Mandamus Act need not rely upon an implied private right of action under any other statute.

IV.

We also reject the government's argument that Soler lacks standing. Soler plainly meets the constitutional requirements for standing. He has alleged an injury in fact, illegal incarceration; that injury is fairly traceable to the INS' alleged policy of delaying deportation hearings until the alien's

sentence has been served; and the injury would be redressed by the relief requested, the holding of a deportation hearing as expeditiously as possible. See *Valley Forge Christian College v. Americans United for Separation of Church and State*, 454 U.S. 464, 472 (1982) (discussing the constitutional standing requirements).

Soler also meets the statutory requirements for standing under both the APA and the Mandamus Act. an individual has standing to bring a claim under the APA if "the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute ... in question." *Association of Data Processing Service Organizations v. Camp*, 397 U.S. 150, 153 (1970). This requirement for standing "is not meant to be especially demanding; in particular,

there need be no indication of congressional purpose to benefit the would-be plaintiff." *Clarke v, Securities Indus. Ass'n*, 479 U.S. 388, 399-400 (1987) (citations omitted); see also *National Wildlife Federation v. Burford*, 871 F.2d 849, 852 (9th Cir. 1989), The standing requirement is satisfied if plaintiff's interest has "a plausible relationship to the policies" underlying the statute. *Clarke*, 479 U.S. at 403. Review is denied only "if the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Id.* at 399.

Soler's claim is not "so marginally related to or inconsistent with the purposes implicit in [Section 701] that it cannot reasonably be assumed that Congress intended to permit the suit." *Id.* To the

contrary, though Section 701 was apparently enacted for the benefit of taxpayers rather than incarcerated aliens, Soler's suit advances the stated congressional purpose of reducing prison overcrowding cause by INS delay. Soler's suit thus has "a plausible relationship to the policies" underlying Section 701. *Id.* at 403.

The Mandamus Act also contains a standing requirement. It may be invoked "to compel [a federal official] to perform a duty owed to the plaintiff." 28 U.S.C. §1361 (emphasis added). As the Seventh Circuit has concluded, a duty is "owed to the plaintiff" if the plaintiff falls within the "zone of interests" protected by the underlying statute. See, *Jarecki v. United States*, 590 F.2d 670, 675 (7th Cir. 1979).

Though far from identical in other respects, both the APA and the Mandamus

Act are "ordinary element[s] of administrative enforcement schemes," *Legal Aid Society*, 608 F.2d at 1332, and both provide a basis for compelling an agency to take action which by law it is required to take. See, e.g., *id.* at 1331 (relying upon both the Mandamus Act and the APA to compel agency action). We see no reason to infer differing standing requirements for these two means of compelling wrongfully withheld agency action. Accordingly, Soler has standing under the Mandamus Act.

CONCLUSION

We reverse and remand to permit Soler to pursue his claims under the Mandamus

Act and the APA.[5] This opinion shall constitute the judgment of the court. The mandate shall issue 14 days from this date. If a suggestion for rehearing en banc is timely filed, the mandate shall be stayed until the full court acts upon the suggestion, at which time the mandate shall issue forthwith.[6]

RYMER, Circuit Judge, dissenting:

I agree that Congress has said what it expects the INS to do, pretty clearly. But I disagree that Soler has made out a

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[5] Soler has also argued the INS has violated the Equal Protection Clause, the Due Process Clause, 8 U.S.C. §1252(a), and that he is entitled to discretionary relief under 8 U.S.C. §1182(c). Because these claims were not presented to the district court and, in any event, appear to be meritless, we do not address them on appeal. *United States v. Greger*, 716 F.2d 1275, 1277 (9th Cir. 1983).

[6] On remand, the district court may wish to consider appointing counsel to assist Soler if, in its judgment, such an appointment would be helpful to the court.

clear claim to relief on account of a duty owed to him, as the Mandamus Act requires. 28 U.S.C. §1361; see *Nova Stylings, Inc. v. Ladd*, 695 F.2d 1119, 1180 (9th Cir. 1983). Federal prisoners were not the intended beneficiaries of section 701 of the Immigration Reform and Control Act of 1986, 8 U.S.C. §1251(i); the legislative history indicates that states, and overcrowded prisons, were. *See* 132 *Cong. Rec.* 89794-95 (daily ed. Oct. 9, 1986), §16909 (daily ed. Oct. 17, 1986); *Gonzalez v. INS*, 867 F.2d 1108, 1110 (8th Cir. 1989). For this reason, I would affirm.

Unlike the majority, I also would not try to fashion a claim under the Administrative Procedure Act. Soler's petition does not assert an APA claim, and we did not ask the government to brief the issue. While we are certainly obliged to construe pro se pleadings liberally, that obligation does not require us to go off

on an untested theory. We could have appointed counsel for Soler and invited as response from the INS. Given that we have done neither, I respectfully dissent.

Supreme Court, U.S.
FILED
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No. 91-300

IN THE
Supreme Court of the United States
OCTOBER TERM, 1991

NATIONAL ASSOCIATION OF
PHARMACEUTICAL MANUFACTURERS,
Petitioner,

v.

LOUIS W. SULLIVAN,
Secretary of Health and Human Services, *et al.*,
Respondents.

On Cross-Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

---

MEMORANDUM IN RESPONSE TO CROSS-PETITION FOR CERTIORARI

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---

MEMORANDUM IN RESPONSE TO CROSS-PETITION FOR CERTIORARI

Barr Laboratories, Inc. ("Barr")[1] is the petitioner in No. 91-81 and a respondent here. Barr concurs in the request of cross-petitioner National Association of Pharmaceutical Manufacturers ("NAPM") that this Court issue a writ of certiorari to review the judgment of the Court of Appeals for the District of Columbia Circuit.

As for the merits, Barr is not averse to a decision that requires the Food and Drug Administration to review *all* abbreviated new drug applications within the 180-day period established by 21 U.S.C. § 355(j)(4)(A).

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[1] Barr Laboratories, Inc. has no parent or subsidiary companies.

Barr points out, though, that in the event *Heckler v. Day*, 467 U.S. 104 (1984), is read to bar relief for the class represented by NAPM, that case does not preclude relief for Barr as an individual party.

Heckler v. Day was a class action on behalf of Vermont residents who had been denied social security disability benefits and had suffered unreasonable delays in the processing of petitions for reconsideration and the scheduling of hearings on their claims. *Id.* at 107-08. The District Court issued an order in favor of the class requiring the Secretary of Health and Human Services to take the requisite actions within specified time periods after appropriate requests were made, *id.* at 109, and the Court of Appeals affirmed. *Id.* at 110.

The statute at issue in *Day* did not specify a time limit for the agency to take the actions in question. *Id.* at 110-11. The District Court nevertheless held that the statute required hearings within a reasonable time, namely 90 days for hearings and 180 days for reconsideration requests. *Id.* at 109-10.

Justice Powell's opinion for the Court found that the failure to specify time limits in the statute had been intentional on the part of Congress. *Id.* at 109-10, 119. Accordingly,

> it would be an unwarranted judicial intrusion into this pervasively regulated area for federal courts to issue injunctions imposing deadlines with respect to future disability claims.

Id. at 119. In a footnote, however, the Court stated that "nothing in this opinion precludes the proper use of injunctive relief to remedy *individual* violations of [the governing statute]." *Id.* at 119 n. 33 (emphasis in original).

This case differs from *Day* in several decisive respects. For one thing, the statute at issue here contains a stated

deadline for agency action. 21 U.S.C. § 355(j)(4)(A) (1988). Second, the Court of Appeals held that the 180-day deadline of section 355(j)(4)(A) is mandatory. Cross-Petition, App. 4a. For these reasons Barr believes that *Day*'s distinction between class and individual relief is inapplicable here, and that both Barr and NAPM's members should be granted relief. Should this Court disagree on that point and decide that relief for the class represented by NAPM is not appropriate, the Court nevertheless should order relief for Barr as an individual aggrieved party.

Respectfully submitted,

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Nos. 91-81 and 91-300

In the Supreme Court of the United States

OCTOBER TERM, 1991

BARR LABORATORIES, INC., PETITIONER

v.

LOUIS SULLIVAN, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS, CROSS-PETITIONER

v.

LOUIS SULLIVAN, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION AND CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether a court has equitable discretion to withhold a remedy in an action under 5 U.S.C. 706(1) of the Administrative Procedure Act to "compel agency action unlawfully withheld or unreasonably delayed."

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In the Supreme Court of the United States

OCTOBER TERM, 1991

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ON PETITION AND CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals, Pet. App. 1a-9a, is reported at 930 F.2d 72.

JURISDICTION

The judgment of the court of appeals was entered on April 16, 1991. The petition for a writ of certiorari was filed on July 15, 1991. The cross-petition was filed on August 16, 1991. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Under the Food, Drug, and Cosmetic Act (the FDCA or Act), no one may introduce a new drug into interstate commerce without receiving approval of a new drug application from the Food and Drug Administration (FDA). 21 U.S.C. 355(a); 21 C.F.R. 5.10(a)(1). A new drug application must demonstrate the drug's safety and effectiveness and therefore typically includes, among other things, controlled clinical studies of the drug's safety and efficacy. 21 U.S.C. 355(b)(1)(A). Persons who wish to distribute generic drugs, *i.e.*, copies of name-brand drugs already approved by FDA, may file "abbreviated" new drug applications. 21 U.S.C. 355(j). An abbreviated application need not reproduce the types of clinical studies on which approval of the name-brand drug was based. In order to make generic drugs available to the public more quickly and at less expense, abbreviated applications need only demonstrate, in lieu of safety and efficacy studies, that the generic drug is "bioequivalent" to the name-brand drug and that the generic drug is properly manufactured and labeled. 21 U.S.C. 355(j)(2)(A).

The FDCA provides that the FDA "shall approve or disapprove" an abbreviated new drug application "[w]ithin one hundred and eighty days of the initial receipt of an application." 21 U.S.C. 355(j)(4)(A). The FDCA does not specify any consequences that will follow if the FDA fails to act on an application within 180 days. Statutory review "from an order of the [FDA] refusing or withdrawing approval of an application under this section" may be obtained by filing, in the petitioner's circuit of residence or "the United States Court of Appeals for the District of Columbia Circuit * * * a written petition praying that the order of the [FDA] be set aside." 21 U.S.C. 355(h).

2. Petitioner, Barr Laboratories, commercially produces generic drugs. In July 1990, it filed a petition in the District of Columbia Circuit, contending that the FDA had not approved or disapproved, within the 180-day time limit, 21 of its abbreviated new drug applications. Petitioner sought a writ of mandamus to compel the FDA to act upon applications pending beyond the 180-day limit and "adhere to the time limits" with respect to pending applications or applications that may be filed in the future. Pet. App. 24a-25a. See generally *id.* at 10a-25a.

The FDA acknowledged that it had not met the statutory time limits and that a lag between the submission of applications and their approval or disapproval would continue to endure in the near future.[1]

---

[1] As the court of appeals noted, the FDA "explain[ed] the lag as the product of a personnel crisis that began in the summer of 1988, when scandal beset its generic drug division, forcing out some employees and diverting others from their usual work." Pet. App. 3a.

Therefore, as the court of appeals noted, the question before the court was "not whether the [FDA] has violated a statutory mandate—it has—but whether [to] exercise [the court's] equitable powers to enforce the deadline." Pet. App. 4a.

To determine whether to exercise its equitable powers, the court considered a number of factors first identified in *Telecommunications Research & Action Center* v. *FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) (*TRAC*).[2] While acknowledging the importance of getting useful drugs into the public's hands as quickly and cheaply as possible, the court emphasized that petitioner had not been singled out for mistreatment by the FDA, and that such delays are endemic in the agency's current circumstances, endured by all drug manufacturers seeking approval for abbreviated drug applications. Pet. App. 4a-6a. Granting the requested relief, the court explained, would do no more than place petitioner at the front of a very long line of similarly situated drug manufacturers: "[A] judicial order

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[2] The six factors identified in *TRAC*, 750 F.2d at 80 (citations and internal punctuation omitted), are as follows:

> (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

putting Barr at the head of the queue simply moves all others back one space and produces no net gain [for the public]." *Id.* at 6a. Thus, because the requested relief would only advance petitioner's own economic interests, would not advance "the cause of equal treatment," *ibid.*, or any of the policy objectives Congress sought to achieve in establishing the abbreviated drug application system, and would interfere with the FDA's ability to achieve other congressional goals, the court declined to issue a writ of mandamus. *Id.* at 7a.

ARGUMENT

1. Petitioner does not seek review of the court of appeals' conclusion that the relief requested would be inconsistent with principles of equity. The sole argument in its petition for a writ of certiorari is that although equitable discretion may govern the issuance of a writ of mandamus, a court lacks equitable discretion under the judicial review provisions of the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq.*, and that the court of appeals was therefore obliged to direct the FDA to act on petitioner's applications within the 180-day limit, no matter how inequitable that result may be. Pet. 11. That question does not warrant review by this Court, for several reasons.

a. Petitioner did not raise in the court of appeals the question presented in the certiorari petition, and the court of appeals did not pass on that question. Petitioner filed this action as an original action in the court of appeals, and the only relief sought by petitioner in that court was a writ of mandamus. The petition filed in the D.C. Circuit by petitioner made that point expressly: "The appropriate remedy for such agency inaction is a writ of mandamus issuing from this Court." Pet. App. 24a. Petitioner did

not claim that it was entitled to an injunction as a matter of law if the court of appeals determined that the FDA had violated the abbreviated new drug application provisions of the FDCA.

Petitioner maintains that it raised this claim in the court of appeals because petitioner contended below that the court of appeals had jurisdiction over this action under the APA. In this regard, petitioner claims that it "sought relief under the APA as well as the All Writs Act, App. 11a (Pet. ¶ 1), but the Court of Appeals treated the two grounds as if they were identical." Pet. 7. That allegation, however, was not sufficient to preserve the claim that petitioner has presented in the certiorari petition. Even if petitioner were correct that the APA provided the court of appeals with jurisdiction over this case, but see page 8, *infra*, that claim does not raise the question that petitioner has asked this Court to review: namely, whether the APA's judicial review provisions divest the courts of the equitable discretion they would otherwise enjoy to grant or withhold relief to compel agency action that is unreasonably delayed.[3]

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[3] Moreover, while petitioner now maintains that the APA supplies a party with a basis for relief that is distinct from the relief available under the All Writs Act, 28 U.S.C. 1651, in the court of appeals petitioner merged the two theories. The only express mention of the APA's judicial review provisions in petitioner's papers in the court below came in a context implying that there are no fundamental differences between relief under Section 706(1) and under the All Writs Act, 28 U.S.C. 1651. See Pet. App. 24a ("FDA's failure to act on [applications] filed by [petitioner] effectively has thwarted this Court's jurisdiction. * * * The appropriate remedy for such agency inaction is a writ of mandamus issuing from this Court. 5 U.S.C. § 706; 28 U.S.C. § 1651; *see Telecommunications Research and Action Center v. FCC*, 750 F.2d 70, 76 (D.C. Cir. 1984).").

This Court has frequently held that "[o]nly in exceptional cases will this Court review a question not raised in the court below." *Lawn* v. *United States*, 355 U.S. 339, 362 n.16 (1958). There are no exceptional circumstances present here. Accordingly, further review is unwarranted.

b. Moreover, there is no conflict among the circuits on the question presented by petitioner. Indeed, not only did the court of appeals not decide that question in this case, no court at any level appears to have addressed the question whether the courts have more, less, or the same degree of equitable discretion to withhold a remedy under the judicial review provisions of the APA than they possess under the All Writs Act (or under the Mandamus Act, 28 U.S.C. 1361). There is no need whatsoever for this Court to address that novel issue in the first instance.

Petitioner contends that *Association of Am. Railroads* v. *Costle*, 562 F.2d 1310 (D.C. Cir. 1977), held "by implication" that "where a finding of unlawful witholding has been made, relief under the APA is required." Pet. 8. An allegation of an intra-circuit conflict, however, is a matter for the court of appeals, not this Court, to resolve. *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957). In any event, *Association of Am. Railroads* does not support petitioner's claim. That case merely compels agency action without discussing whether in an appropriate case equitable considerations could warrant withholding injunctive relief. 562 F.2d at 1321-1322.[4]

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[4] In a different section of the opinion, *Association of Am. Railroads* in fact suggests that an injunction would not have to issue as a matter of law without regard to equitable factors: "The courts are, of course, concerned with the consequences of the decisions which they render; they will examine these

c. In addition, the judicial review provisions of the APA do not apply in the posture of this case. Accordingly, the question presented in the certiorari petition would not be properly before this Court even if petitioner had raised that question in the court below.

As we have noted, Congress provided for judicial review of "an order of the [FDA] refusing or withdrawing approval of [a new drug] application," 21 U.S.C. 355(h). Even if the judicial review provisions of the APA apply to review from an FDA order refusing or withdrawing approval of a new drug application, petitioner has not sought review of such an order. Instead, petitioner seeks judicial review of the FDA's pre-order delay. The D.C. Circuit's decision in *TRAC* analyzes the jurisdictional questions peculiar to claims concerning agency delay when judicial review of final agency action is committed in the first instance to the court of appeals. The *TRAC* decision also explains why the review provisions implicit in the All Writs Act, not the APA, govern cases in this posture.[5]

First, *TRAC* noted that the APA "unquestionably does not confer an independent grant of jurisdiction," 750 F.2d at 76; instead it grants parties a cause of action. See also *Califano* v. *Sanders*, 430 U.S. 99

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consequences as a factor in determining whether to grant the relief requested by the complaining party in a particular case." 562 F.2d at 1319. The court also believed that it had the power to be flexible regarding the date that the court could set for compliance with its mandate. *Id.* at 1321-1322.

[5] *TRAC* noted that the prior decisions of the D.C. Circuit had been "somewhat inconsistent and may be confusing for litigants" concerning the jurisdiction over interlocutory appeals from agency action. 750 F.2d at 74.

(1977). Second, in *TRAC*, as in this case, judicial review of agency action was committed originally and exclusively to the court of appeals. But since "a statute which vests jurisdiction in a particular court cuts off original jurisdiction in other courts in all cases covered by that statute," 750 F.2d at 77, the statute that generally grants district courts jurisdiction over claims as to which the APA supplies a cause of action for adverse agency action, 28 U.S.C. 1331, does not provide a jurisdictional predicate for APA review, because review lies in the courts of appeals. Third, in *TRAC*, as in this case, the statutory jurisdiction is limited. 750 F.2d at 74. In the statutory scheme at issue in *TRAC*, jurisdiction extended only to "final agency action." But in a challenge to agency action unreasonably delayed "there is no final order—indeed, the lack of a final order is the very gravamen of the petitioners' complaint." *Id.* at 75. Therefore, in *TRAC*, as in this case, there is no general jurisdictional basis for review of claims of agency delay.

As noted in *TRAC*, however, the absence of a general jurisdictional basis does not mean that the court lacks power to review petitioner's claim. Under the All Writs Act, the courts of appeals "may issue all writs necessary or appropriate in aid of their respective jurisdictions." 28 U.S.C. 1651. It is well established that the All Writs Act "empowers a federal court to issue writs of mandamus necessary to protect its prospective jurisdiction." *TRAC*, 750 F.2d at 76. *TRAC* therefore held that since agency delay might defeat the court's obligation to review agency decisions on the merits, the All Writs Act authorized the court of appeals to review claims of agency delay

and, in appropriate circumstances, to issue a writ of mandamus to compel agency action.[6]

The reasoning of *TRAC* supports review by the court of appeals of petitioner's claims. The court of appeals has prospective jurisdiction over the FDA's approval or disapproval of petitioner's abbreviated applications under 21 U.S.C. 355(h). The All Writs Act empowers the court to protect that prospective jurisdiction, but confines a court's authority to "all writs necessary or appropriate." Thus, because a writ of mandamus is equitable in nature, the right to a remedy by issuance of that writ is subject to the sound equitable discretion of the court. Otherwise, the writ would cease to be a writ of mandamus. In sum, where judicial review of final agency action lies initially in a court of appeals, a claim of unreasonable agency delay is reviewed under the All Writs Act, not the APA. Thus, the question presented by petitioner —whether a court has discretion under the APA to

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[6] Under the *TRAC* analysis, it makes no difference, for jurisdictional purposes, whether the claim of agency delay is based upon an express statutory deadline or upon an implicit obligation to complete final action within a reasonable amount of time. *TRAC* holds that in assessing the factors that bear upon whether a court should issue a writ of mandamus, a statutorily established deadline "may supply content for [a court-determined] rule of reason." 750 F.2d 80. But the presence or absence of a statutory "deadline" does not provide a jurisdictional basis for review apart from the All Writs Act. Accordingly, for purposes of determining whether judicial review of petitioner's claim is under the APA or the All Writs Act, petitioner does not advance its case by contending that the presence of a statutory deadline converts this from an "unreasonably delayed" action into an "unlawfully withheld" action. 5 U.S.C. 706(1). In either case, FDA delays are reviewable only under the All Writs Act.

refuse to compel agency action unreasonably delayed —has no bearing on the correctness of the court of appeals' decision in this case.[7]

d. In any event, even if the APA judicial review provisions applied to this case, the court of appeals' decision would be correct. The APA provides that a court "shall * * * compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. 706(1). Relying upon the use of the word "shall" in that statute, petitioner argues that the statute was intended to alter the available scope of judicial review of claims of agency delay by eliminating the discretion that courts traditionally possess to withhold an equitable remedy. But even if that term were read as mandatory, courts would be obliged to compel action only for those delays that are "unreasonabl[e]," and that term can be fairly read to embrace the kinds of equitable considerations taken into account by courts in determining whether to issue a writ of mandamus.

This reading is strongly supported by the APA's legislative history. Although Congress did not directly address the scope of a court's discretion under Section 706(1), the House and Senate Committees, and individual congressmen, consistently stated that 5 U.S.C. 706(1) was intended as a "restatement of the scope of review" then existing. S. Doc. No. 248, 79th Cong., 2d Sess. 39 (1946); *id.* at 84 ("[W]e do

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[7] That question could properly be presented in any action seeking to compel agency action unreasonably delayed in which jurisdiction lay originally in the district court. For example, review of some categories of final FDA action is not committed to the courts of appeal. There, jurisdiction lies in the district courts under 28 U.S.C. 1331. See, *e.g.*, *Cutler* v. *Hayes*, 818 F.2d 879, 887 n.61 (D.C. Cir. 1987). In such a case, the APA's judicial review provisions would govern the relief available.

not believe the principle of review or the extent of review can or should be greatly altered. * * * [T]he scope of review should be as it now is.") (remarks of Rep. McFarland); *id.* at 224 ("[The APA] restates the law governing judicial review of administrative action."); *id.* at 278 (interested parties have a right to "compel agencies to act where they *improvidently* refuse to act.") (emphasis added). In response to a request by Congress for comments on the bill prior to passage of the APA, the Attorney General, referring to 5 U.S.C. 706(1), stated that "[t]his section, in general, declares the existing law concerning judicial review." S. Doc. No. 248, *supra*, at 229. As the Attorney General explained, *id.* at 415:

> Section 10 as to judicial review does not * * * make any real changes in existing law. * * * It is an attempt to restate in exact statutory language the doctrine of judicial review as expounded in various statutes and as interpreted by the Supreme Court. I know that some agencies are quite concerned * * * that it will change the existing doctrine of judicial review * * *. I feel sure that should this section be given the interpretation which is intended, namely, that it is merely a restatement of existing law, there should be no difficulty for any agency.[8]

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[8] Because of the substantial role the Department of Justice played in aiding Congress's consideration of the APA, significance attaches to a Department memorandum furnished by the Attorney General. See also *Attorney General's Manual on the Administrative Procedure Act* 108 (1947 & photo reprint 1979) ("[The clause] authorizing a reviewing court to 'compel agency action unlawfully withheld or unreasonably delayed', appears to be a particularized restatement of existing judicial practice under section 262 of the Judicial Code (28 U.S.C. 377). *Safeway Stores, Inc.* v. *Brown*, 138 F.2d 278

Because the APA was intended to restate the existing law concerning judicial review, 5 U.S.C. 706(1) may not be construed as fundamentally altering the scope of review of claims of agency delay. But, at the time the APA was enacted, review of claims of agency delay was available only upon petition for a writ of mandamus.[9] Therefore, courts possess the same discretion under 5 U.S.C. 706(1) to withhold a remedy, when relevant considerations would render the relief inequitable, as they would in entertaining a petition for a writ of mandamus.

Relying upon *Sierra Club* v. *Thomas*, 828 F.2d 783, 793 (D.C. Cir. 1987), petitioner argues that when "a statutory mandate has been violated, the agency action has been 'unlawfully withheld' * * * [and only] in the absence of a statutory deadline does the 'unreasonable delay' test come into play." Pet. 10. Petitioner apparently contends that one test is appropriate for "unreasonably delayed" cases and another for "unlawfully withheld" cases. But petitioner has misread *Sierra Club*. That case gave as an example of action unlawfully withheld for APA purposes, not missing a statutory deadline, but agency recalcitrance in the face of statutory provisions "that require an agency to take specific action when certain preconditions have been met," *i.e.*, failing to perform a specifically mandated duty. 828 F.2d at 793. By con-

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(E.C.A., 1943)."). The decision in *Safeway Stores* concerned claims of agency delay under the Emergency Price Control Act. Final orders were subject to review in the courts of appeals. *Safeway Stores* held that, under the All Writs Act, such claims might be reviewed in a petition for a writ of mandamus.

[9] See, *e.g.*, *Safeway Stores, Inc.* v. *Brown*, 138 F.2d 278 (Emer. Ct. App.), cert. denied, 320 U.S. 797 (1943).

trast, as *Sierra Club* clearly states, "[w]hat differentiates 'unreasonable delay' from 'unacknowledged final action' [which constitutes action that has been unlawfully withheld for APA purposes] is that the petitioner who pleads the former concedes that the agency is still analyzing the matter, but complains that the process is taking too long." *Id.* at 794. Petitioner does not contend that the FDA's delay is a de facto denial of their application or, for some other reason, amounts to "unacknowledged final action." Its complaint throughout has been that the review process is taking too long.[10]

In any event, the "unlawfully withheld" provision of the APA "means that the court *may* compel the agency to act where it has 'unlawfully withheld' action," not that it must. S. Doc. No. 248, *supra*, at 40 (emphasis added). That provision no more withdraws equitable discretion from the courts than does the APA's "unreasonably delayed" provision.

2. Cross-petitioner seeks review of the court of appeals' decision that petitioner was not entitled to a writ of mandamus. The cross-petition was not filed until August 16, 1991, however, and therefore is untimely as a certiorari petition. The cross-petition is timely only by virtue of this Court's Rule 12.3 and therefore should be denied without further consideration if the petition is denied. Sup. Ct. R. 13.5.

In any event, the cross-petition should be denied even if the petition were granted. The balancing conducted by the court of appeals is fact-bound; it is limited to the present posture of this case, Pet. App. 9a ("We thus dismiss the suit, but invite [petitioner]

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[10] Petitioner also relies on *Environmental Defense Fund, Inc.* v. *Costle*, 657 F.2d 275 (D.C. Cir. 1981), but that case did not decide the question presented here.

to refile should circumstances arise that would change the outcome of our analysis."); and it is correct, for the reasons given by that court. Cross-petitioner has identified no aspect of that decision warranting this Court's review.

There is also no merit to cross-petitioner's claim that the decision below conflicts with *Soler* v. *Scott*, No. 89-16051 (9th Cir. Aug. 1, 1991). That case held that a time limit established by the Immigration Reform and Control Act of 1986 was mandatory, not hortatory. Cross-Pet. App. 11a. *Soler* does not address, as does the decision below, whether equitable considerations warrant withholding a remedy for a violation of a statutory deadline.

CONCLUSION

The petition and cross-petition for a writ of certiorari should be denied.

Respectfully submitted.

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